

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

BLUEWILLOW BIOLOGICS, INC.;
ROBIN ROE 1 through 10, gender
neutral fictitious names, and; ABC
CORPORATION 1 through 10 (fictitious
names).

Hon. F. Kay Behm

Defendants.

**DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW
BIOLOGICS, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION
TO EXCLUDE THE EXPERT REPORT AND TESTIMONY OF
AMIRALI Y. HAIDRI**

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I. INTRODUCTION

As established in BlueWillow's Motion (ECF 56), Amirali Y. Haidri, Esq.'s ("Haidri") Report and proposed testimony is a textbook example of inadmissible legal opinion under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). First, his Report consists almost entirely of legal argument from an attorney that categorically would not assist the trier of fact. Second, Haidri does not qualify as an expert having at least ordinary skill in the relevant art. Third, Haidri's Report does not identify a sufficiently reliable methodology and he relies on fundamentally erroneous legal assumptions and unverified factual predicates.

Trutek states that Haidri intends to testify on the following categories: (1) the chemistry, chemical and physical properties of the formulations of the '802 Patent and the prior art; (2) patent office procedure generally; (3) a person of ordinary skill in the art; (4) patentable subject matter, written description, and enablement of the '802 Patent claims; (5) anticipation and obviousness of the '802 Patent claims; (6) rebuttal of Dr. Amiji's opinions on invalidity; and (7) rebuttal of Dr. Amiji's purported misstatements of patent law. ECF 72 at 9. None of these categories are proper areas for expert testimony from Haidri. Despite Trutek's attempt to redefine the field of the invention (ECF 72 at 4-8) to fit Haidri's experience, including the new "qualifications" it has belatedly manufactured for Haidri, he is not qualified to testify as a technical expert (categories 1, 3, 4, 5, 6).

His proposed testimony is also inadmissible given that his Report consists entirely of legal arguments and he applied unverified factual assumptions and incorrect legal standards when reaching his conclusions. Haidri's alleged expertise and testimony as a patent lawyer is neither needed, nor appropriate (categories 2 and 7). And, the Court has already established the level of the person of ordinary skill in the art ("POSA") for the '802 patent (category 3).

II. ARGUMENT

A. Haidri Is Not Qualified as a Technical Expert for Patent Invalidity

As Trutek previously argued, and as adopted by the Court, the relevant art for the '802 patent is pharmaceutical formulation. *See* ECF 53 at 8 (citing ECF 40 at 12). According to Trutek's definition proposed during claim construction, the POSA "must be a technician with several years of experience as a [pharmaceutical] formulator." ECF 40 at 13. Thus, Trutek's new description of the field of invention as "organic chemistry"¹ is directly contradicted by its own positions taken in the litigation. There can be no argument that Haidri does not possess the relevant experience. ECF 56 at 17-20. By Trutek's own admissions, Haidri has "neither created nor tested pharmaceutical formulations." ECF 72 at 13. His only apparent laboratory experience was a summer job 55 years ago before obtaining his B.S.

¹ Organic chemistry is a different field: the study of carbon compounds found in living things. <https://www.merriam-webster.com/dictionary/organic%20chemistry>.

degree. ECF 72 at 12; ECF 72-3 at ¶ 7. Trutek does not explain how that job experience, lasting only a few months, is related to pharmaceutical formulation.² Trutek’s suggestion that expertise in “pharmaceutical formulation,” “infectious diseases” and “topical drug application” are “irrelevant and unnecessary” (ECF 72 at 8) are inconsistent with the ’802 patent claims as well, which require applying a formulation “to the skin or tissue of nasal passages” to “inhibit[] harmful particulate matter from infecting an individual” (ECF 56-3 at 32, 34). Finally, Federal Circuit case precedent makes clear that qualifications merely arising from patent prosecution does not qualify that person to speak to patent invalidity. *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, at 1362, n.4 (Fed. Cir. 2008). Nor does Haidri’s experience as a trademark associate or trial lawyer establish his qualifications as a technical expert.³

It is an abuse of discretion for a Court to permit a witness to testify as an

² This job was not listed on any CV previously provided to BlueWillow, nor was it described in his expert report. ECF 56-3; 71-2. The same is true for Haidri’s alleged employment as a “laboratory demonstrator.” BlueWillow was not provided the opportunity to depose Haidri on these alleged qualifications and it would be prejudicial to allow Trutek to rely on this late-disclosed information.

³ It is concerning that Trutek believes that Haidri’s experience as trial counsel for Trutek in a prior litigation involving the ’802 patent qualifies him to serve as a technical expert here. Not only does the Model Code of Professional Ethics inveigh against counsel participating as a witness, courts generally disapprove of the practice absent necessity. *See Universal Athletic Sales Co. v. American Gym, Recreational & Athletic Equip. Corp.*, 546 F.2d 530, 539 (3rd Cir. 1976). Trutek has demonstrated no such necessity. Further, it is clear error for a court to place controlling weight as to patent validity on testimony from such a person. *Id.*

expert on patent invalidity unless that witness is qualified as an expert in the pertinent art. *See Sundance*, 550 F.3d at 1363. Clearly, Haidri is not qualified “by knowledge, skill, experience, training, or education” to testify from the viewpoint of a POSA, and should not be permitted to testify on issues of invalidity. *See Fed. R. Evid. 702*. Thus, Haidri should not be permitted to testify about: (1) chemistry, chemical properties, and physical properties of the ’802 Patent and prior art formulations; (3) the POSA; (4) patentable subject matter, written description, and enablement of the ’802 Patent; (5) anticipation and obviousness of the ’802 Patent; or (6) rebuttal of Dr. Amiji’s invalidity opinions on the ’802 Patent.⁴ ECF 72 at 9.

Perhaps now realizing that Haidri lacks any qualifications in the previously argued subject area of the ’802 patent, Trutek shifts course and now argues that the relevant subject area is organic chemistry, not pharmaceuticals. ECF 72 at 4-7. All these arguments should be ignored.⁵ The Court has already determined the field of art is pharmaceutical formulation. It is a “reversible error” for the Court to later apply an incorrect definition of a POSA. *See Custom Accessories*, 807 F.2d at 963.

⁴ An expert may only testify on opinions and information contained in his expert report. Fed. R. Civ. P. 26(e) and 37(c)(1). Contrary to Trutek’s assertions, expert reports do not simply serve to refresh recollection or impeach. ECF 70 at 10.

⁵ Mr. Wahi’s background is not relevant as the qualifications of the actual inventor is not determinative when considering the qualifications of a POSA. *See Custom Accessories, Inc. v. Jeffrey-Allen Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

B. Haidri's Proposed Testimony Is Inadmissible Legal Argument

The remaining topics on which Trutek proposes Haidri will testify are (2) patent office procedure; and (7) rebuttal of Dr. Amiji's purported misstatements of patent law. This testimony is neither appropriate, nor permissible. Trutek has not identified any reason why Haidri is needed to testify as to patent office procedure and Haidri's report does not provide any insight on this topic that would "assist the trier of fact." Fed. R. Evid. 702. BlueWillow is not asserting any defense related to the prosecution of this patent and as such, testimony on this topic would only confuse the jury. *EEOC v. Kaplan Higher Educ. Corp.*, 748 F.3d 749, 752 (6th Cir. 2014) (proponent of expert testimony bears burden of establishing admissibility).

Haidri's report and proposed testimony also goes well beyond explaining patent office procedure. ECF 56 at 5-9, 13-16. Pages 3-5 recite case law and statutes and page 6 discusses the *district court standard of proof*. ECF 56-3. Haidri makes conclusions based on this *district court standard*, which has nothing to do with patent office procedure: "In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101." *Id.* at 42. Pages 9-24 of Haidri's report is the only section that even touches on patent office procedure, but it is a confusing amalgamation of legal standards and case law regarding requirements for a patent to issue and for a patent to later be found invalid.

Trutek asserts Haidri is merely offered to rebut “incorrect legal opinions proffered by Amiji.” ECF 72 at 9. Dr. Amiji’s report is not the subject of this motion, only Haidri’s report and proposed testimony. Nevertheless, BlueWillow explained why Dr. Amiji does not provide impermissible legal opinions. ECF 73.

While *technical experts* are permitted to offer their opinion on the ultimate issue, “recitation of legal principles . . . is not appropriate expert testimony.” *Killion v. KeHE Distribs., LLC*, 751 F.3d 574, 592-93 (6th Cir. 2014); *see also Lanard Toys Ltd. v. Anker Play Prods., LLC*, No. CV 19-4350, 2020 WL 6873647 (C.D. Cal. Nov. 12, 2020). “Further, it is well-settled that experts are prohibited from testifying as to the content or application of the law.” *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 96 (S.D.N.Y. 2001) (citing *United States v. Duncan*, 42 F.3d 97, 103 (2d Cir.1994); *In re IPO Sec. Litig.*, 174 F. Supp. 2d 61, 63–68 (S.D.N.Y. 2001)). Haidri lacks technical experience to testify on invalidity issues, and it is the role of the judge to instruct the jury as to the law. As such, Trutek’s rationale (ECF 72 at 10) that “[Haidri’s case citations] were presented in his report to show where Amiji misinterpreted the law” do not render his legal opinions and testimony admissible. *See also Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1297 (Fed. Cir. 2012) (“To be sure, many lawyers have technical training, but it is the technological experience in the field of the invention that guides the determination of obviousness, not the rhetorical skill

or nuanced advocacy of the lawyer.”); *Formax, Inc. v. Alkar-Rapidpak-MP Equip., Inc.*, No. 11-C-298, 2014 WL 3057116, at *3 (E.D. Wis. July 7, 2014) (jury is instructed on substantive law and burden of proof by the Court).

C. Haidri Failed to Employ a Reliable Methodology

Trutek’s Response fails to even address most of BlueWillow’s arguments that Haidri relied on incorrect legal standards and unsupported factual assumptions, including the flawed “no reasonable examiner” standard, why an expert may not speculate about the examiner’s state of mind, and Haidri’s reliance on “facts” provided by counsel that could not be independently verified. ECF 56 at 22-25.

Mr. Haidri’s testimony should be excluded in its entirety.

Dated: May 30, 2023

Respectfully submitted

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CERTIFICATE OF SERVICE

I hereby certify that, on May 30, 2023, I filed the foregoing document and this Certificate of Service with the Court using the ECF system.

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